NOT FOR PUBLICATION

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

WEDGEWOOD VILLAGE PHARMACY, LLC, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil No. 22-cv-02649 (KMW/SAK)

Appearances:

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WILLIAMS, District Judge

MEMORANDUM OPINION

I. INTRODUCTION

This matter comes before this Court pursuant to Plaintiff Wedgewood Village Pharmacy, LLC's ("Plaintiff") Emergent Application for Temporary Restraining Order and Order to Show Cause Why the Court Should Not Issue A Preliminary Injunction (ECF No. 3) ("Application") preventing Defendant U.S. Food and Drug Administration ("FDA") from issuing any press release

or statement regarding its March 2022 inspection.[1] Defendants FDA, Xavier Becerra, and Dr. Robert M. Califf (collectively, "Defendants") filed an Opposition (ECF No. 13) to the Application, and Plaintiff filed a Reply (ECF No. 15). Having considered the parties' submissions and arguments made during oral argument held on May 16, 2022, and for the reasons set forth below, the Court will deny Plaintiff's Application.

II. BACKGROUND

The following facts are alleged in Plaintiff's Application and the exhibits appended thereto.[2] Plaintiff is a veterinary 503A animal-health compounding pharmacy. Decl. of Anthony Grzib, ECF No. 3-4 at ¶ 3. Plaintiff is the largest compounding pharmacy devoted to animal health in the United States and serves over 50,000 prescribers and hundreds of thousands of patients in the United States every year.[3] Verified Compl., ECF No. 1 at ¶¶ 1-2. As a compounder, Plaintiff, through doctors and pharmacists, combines, mixes, or alters ingredients to create a medication tailored for the specific needs of an individual patient. *Id.* at ¶¶ 28-29. Moreover, as a compounder, Plaintiff is subject to different regulations than drug manufacturers, but remains regulated by the FDA and the Federal Drug and Cosmetic Act ("FDCA"). Pl.'s Br. in Support of App., ECF No. 3-1 at 9-14. The FDA is tasked with enforcing the FDCA and protecting the public health. Defs.' Opposition to App., ECF No. 13 at 4. To this end, "the

[1] Pursuant to Federal Food, Drug, and Cosmetic Act, "[t]he Secretary may also cause to be disseminated information regarding food, drugs, devices, tobacco products, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department." 21 U.S.C.A. § 375 (West).

[2] Because a more detailed recitation of the facts is warranted to fully appreciate the issues presented and argued to the Court, the Court has supplemented the facts with reference to the Verified Complaint.

[3] In addition to serving the animal-health market, Plaintiff also serves the human-health market; however, its current operations include only 1% human-health compounding. Verified Compl., at ¶ 60.

FDCA gives FDA authority to inspect manufacturing facilities and observe conditions indicating that a drug is adulterated." *Id.* (citing 21 U.S.C. § 374(b)). In carrying out its mission as it relates to compounding pharmacies, the FDCA prohibits "'[t]he adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce,'" Pl.'s Br. in Support of App., at 13 (quoting 21 U.S.C. § 331(b)), and the FDA has issued guidance for insanitary conditions at compounding facilities "to guide compounding facilities on the FDA's implementation of the adulteration and insanitary conditions provisions of the FDCA." Verified Compl., at ¶ 49. Crucially, it is undisputed that the FDA is authorized to inspect 503A pharmacies, such as Plaintiff. Pl.'s Br. in Support of App., at 11.

In November 2021, Plaintiff discovered an imperfection in a Twist-a-Dose ("TAD") product which is used for the application of certain medication to animals. Grzib Decl., at ¶ 19. Specifically, mold was discovered, causing Plaintiff to initiate a voluntary recall of all its TAD products on the market. *Id.* at ¶¶ 20-21.

Between March 14, 2022 and March 24, 2022, the FDA initiated and conducted an inspection of Plaintiff's Swedesboro facility ("Inspection"). *Id.* at ¶ 23.[4][5] Plaintiff cooperated with the FDA during the Inspection and afforded the FDA access to the facility. Pl.'s Br. in Support of App., at 18. On March 24, 2022, the FDA concluded the Inspection and issued a Form 483[6] outlining its findings and conclusions. Grzib Decl., at ¶ 27. Plaintiff asserts that the

[4] Notably, the parties, and thus the Court, refer interchangeably to inspection and investigation.

[5] According to the Verified Complaint, the FDA indicated the Inspection was prompted because of Plaintiff's February voluntary TAD recall and also to further assess the corrective actions Plaintiff was instructed to implement in response to a 2015 FDA inspection. Verified Compl., at ¶ 85.

[6] According to the Verified Complaint, "[a] 483 is the report issued to management after an FDA inspection that lists observations of conditions of the facility. These 'observations' identify potential areas of noncompliance." Verified Compl., at ¶ 90, FN 7.

majority of the observations within the Form 483 pertained to minor incidents (and do not demonstrate insanitary conditions). *Id.* at ¶¶ 29-40. On the other hand, Defendants indicate that the inspectors observed "serious insanitary conditions," and concluded that, among other things, Plaintiff had neither identified the source of the mold contamination nor resolved the mold contamination that had prompted the February 2022 voluntary recall. Defs.' Opposition to App., at 6. Defendants further explain that the FDA observed, among other things, vermin where Plaintiff stored production materials, as well as dead insects in an area where Plaintiff stored syringes, vials, and tubing. *Id.*

On April 28, 2022, the FDA and Plaintiff discussed the FDA's observations, and the FDA recommended that Plaintiff recall all nonsterile human- and animal-health compounds within expiry from the Swedesboro pharmacy. Grzib Decl., at ¶ 41. Plaintiff requested a targeted recall, rather than a recall of all the nonsterile products. *Id.* at ¶ 48; Pl.'s Br. in Support of App., at 23. However, on May 4, 2022, the FDA rejected Plaintiff's request and indicated there would not be an additional meeting among the two parties. Grzib Decl., at ¶¶ 49-50; *see also* Exhibit E to the Grzib Decl. According to the Application, the FDA demanded Plaintiff issue the recommended recall by May 5, 2022. *See* Exhibit E to the Grzib Decl. Plaintiff now requests the Court enjoin the FDA from releasing a Section 705(b) notice ("Notice"), which Plaintiff describes as a notice "'warn[ing] patients and health care professionals' not to use the company's products," or any press release related to the Inspection until the Court can address the merits of the case. Pl.'s Br. in Support of App., at 22. Plaintiff concludes and is likely correct that such a notice is being considered and may be imminent. *Id.* at 23-24; *see also* Exhibit E to the Grzib Decl.

On May 5, 2022, Plaintiff filed the Verified Complaint, alleging the following claims: (1) violation of the Administrative Procedures Act, 5 U.S.C. § 706(a) ("APA") asserting the FDA acted in an arbitrary and capricious way by providing no explanation of the standards applied to make its Form 483 conclusions; (2) violation of the APA asserting the FDA acted contrary to law by misapplying certain regulatory standards to Plaintiff as a compounding pharmacy; and (3) retaliation for Plaintiff's protected speech in challenging certain FDA actions by filing the Notice. Verified Compl., at ¶¶ 126-151.

That same day, Plaintiff filed the Application seeking to enjoin the FDA from "(i) printing or publishing any press release or statement regarding its investigation of Wedgewood; and (ii) retaliating against or otherwise punishing Wedgewood for initiating this action." Proposed Order, ECF No. 3-2 at 3. In the Application, Plaintiff argues that it is likely to prevail on the merits first because the FDA-threatened issuance of the Notice is a final agency action that is arbitrary and capricious in violation of the APA. Pl.'s Br. in Support of App., at 25-30. Plaintiff asserts that the FDA has not explained the standards or analysis to warrant the recall and that the recall relies on improper standards not applicable to Plaintiff as a compounder. *Id.* at 30-35. Plaintiff also claims it will prevail on the merits because the threatened Notice constitutes unlawful retaliation against Plaintiff for exercising its First Amendment right by challenging and criticizing the FDA's conduct. *Id.* at 35-37. Next, Plaintiff argues that it will be irreparably harmed without an injunction to prevent the issuance of a notice or press release. Specifically, Plaintiff indicates that if the FDA publicizes the Notice or any statement regarding the Investigation, Plaintiff will suffer serious harm to its business, as well as loss of goodwill among its customers. *Id.* at 37-38. Finally, Plaintiff asserts that the balance of equities weighs in favor of granting the

injunction, and that an injunction against the FDA would serve the public interest because the issuance of the broad recall would compromise Plaintiff's patients' ongoing care and access to medications. *Id.* at 39.

On May 10, 2022, Defendants filed the Opposition to Plaintiff's Application. In the Opposition, Defendants argue that Plaintiff failed to satisfy the requirements to warrant the "extraordinary relief" of a preliminary injunction. Defs.' Opposition to Application, ECF No. 13 at 7. As an initial matter, Defendants assert that Plaintiff has failed to demonstrate its likelihood of success on the merits. First, Defendants argue that Plaintiff's claims are not ripe because the potential issuance of the Notice or other public notification does not constitute an agency action and is not a "final action" to warrant judicial review. *Id.* at 8-18. Defendants emphasize that no notice or press release has been issued and the contents of any potential public notification is currently unknown. *Id.* Second, Defendants assert that Plaintiff's claims are fundamentally meritless because (i) the FDA has the authority to issue the Notice, (ii) the FDA did not apply an improper standard when inspecting Plaintiff's Swedesboro facility, and (iii) Plaintiff's First Amendment claim fails because it has not demonstrated that the FDA had a retaliatory motive to issue the Notice or that the retaliatory motive is the but-for cause for the issuance of the Notice. *Id.* at 18-29. Defendants continue in their opposition to the injunction by claiming Plaintiff has not shown that it would suffer irreparable harm because Plaintiff's alleged harm is based on speculation about the potential Notice or press release, Plaintiff has not demonstrated it would suffer economic harm, and moreover, any harm that could result from the Notice has already occurred by Plaintiff's filing of this suit, effectively publicizing the potential recall. *Id.* at 29-32. Finally, Defendants assert that the balance of equities and the public interest weigh against the

issuance of a preliminary injunction because there is significant public interest in informing the general population about the results of the FDA's Investigation. *Id.* at 32-34.

On May 13, 2022, Plaintiff filed a Reply to Defendants' Opposition, which largely responds to Defendants' arguments and reiterates many of the points within its original Application. Plaintiff first argues that it is likely to succeed on the merits, asserting the Court has subject matter jurisdiction because the FDA is poised to issue the Notice absent judicial intervention, the Notice constitutes a reviewable agency action with judicial review finding the issuance violates the APA, and additionally that Plaintiff is likely to succeed on its First Amendment claims. Pl.'s Reply, ECF No. 15 at 1-11. Next, Plaintiff asserts that the Notice "is poised to issue as night follows days, and will irreparably damage Wedgewood's reputation, business, and patients," and will cost Plaintiff goodwill and market share that are "unrecoverable," thereby constituting irreparable harm. *Id.* 12-13. Finally, Plaintiff argues that the Notice will only trigger "a false and dangerous alarm" and that "preserving the status quo poses no real threat to anyone" and therefore, the public equities favor preserving the status quo while the Court assesses the merits of the case. *Id.* at 14.

III. DISCUSSION

A. The Matter is Not Ripe for Judicial Action

"Article III of the Constitution limits the jurisdiction of federal courts to 'Cases' and 'Controversies.'" *Lance v. Coffman*, 549 U.S. 437, 439 (2007). Accordingly, as a threshold jurisdictional matter, a declaratory judgment action must present an actual case or controversy. *Luis v. Dennis*, 751 F.2d 604, 607 (3d Cir. 1984). In order to present an actual case or controversy, "[t]he controversy must be definite and concrete, touching the legal relations of parties

having adverse legal interests. It must be a real and substantial controversy admitting of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227, 240-41 (1937) (internal citations omitted).

A critical aspect of the Article III case or controversy doctrine is that the matter is ripe for judicial action. "[I]n the context of judicial review of administrative actions, the Supreme Court has been reluctant to apply declaratory judgment and injunctive remedies 'unless these arise in the context of a controversy 'ripe' for judicial resolution.'" *Health Sci. Funding LLC v. The United States Food & Drug Admin. & Stephen Ostroff*, No. CV 15-5635 (CCC-MF), 2016 WL 3078748, at *3 (D.N.J. May 31, 2016) (quoting *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 148 (1967)). The Supreme Court has stated:

> [The] basic rationale [of the ripeness doctrine] is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.

Abbott Lab'ys, 387 U.S. at 148-49. "The ripeness doctrine prevents interference with the acts of an administrative agency except where 'a specific 'final agency action' has an actual or immediately threatened effect.'" *Den-Mat Corp. v. U.S., Food & Drug Admin.*, No. CIV. A. MJG-92-444, 1992 WL 208962, at *2 (D. Md. Aug. 17, 1992) (quoting *Lujan v. National Wildlife Fed'n,* 479 U.S. 871, 110 S.Ct. 3177, 3191 (1990)). The Supreme Court has established two factors that courts should examine when determining whether a case is ripe for review: (1) whether the issues in the case are fit for judicial resolution, and (2) whether the parties will suffer hardship due to the withholding of court consideration. *Abbott Lab'ys*, 387 U.S. at 149. Specifically,

when considering whether an administrative action is ripe for judicial review, courts are instructed to consider whether review is being sought of "'final agency action' within the meaning of § 10 of the Administrative Procedure Act, 5 U.S.C. § 704, as construed in judicial decisions." *Id.* Moreover, "the fitness of the issues for judicial resolution depends on whether the issue tendered is a purely legal one," whereby if the case requires factual development within the context of an administrative record, "it is not fit for judicial resolution." *Health Sci. Funding LLC*, 2016 WL 3078748, at *4 (citing *Abbott Lab'ys*, 387 U.S. at 149).

The Application seeks an injunction to prevent the FDA from issuing any press release or Notice informing the public about the results of the Inspection. The requested relief cannot be granted for three paramount reasons. *First*, the plain reading of the APA precludes the interpretation of the statements as agency action. The APA defines agency action to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C.A. § 551 (West). The APA affords the Court judicial review over final agency action. 5 U.S.C.A. § 704 (West). The yet to be issued notice or press release is not agency action and cannot be final action because the statements have not been released, thus, factual development is required and judicial review would be premature.

Second, fundamental to the Court's authority to review agency action under the APA is the ability to actually and meaningfully review the challenged action. This analysis is therefore predicated on the agency action having actually occurred. Here, Plaintiff's Application asks this Court for an advisory opinion concerning a potential and theoretical publication that the FDA *may* issue in the future. No publication has been presented for review, thus reducing the Court's

review to a hypothetical notice or press release. The Court simply cannot review action that has not yet been taken.

Third, even if the Court were to find that the issuance of the Notice or press release is imminent, the content and potential ramifications of any said publication remain purely hypothetical and speculative without the ability to review the content of these documents. Accordingly, the Court finds that there is no agency action – let alone "final agency action" – within the meaning of the APA.

B. Injunctive Relief is Not Warranted

"[T]o obtain a preliminary injunction the moving party must show as a prerequisite '(1) a reasonable probability of eventual success in the litigation, and (2) that it will be irreparably injured ... if relief is not granted.... [In addition,] the district court, in considering whether to grant a preliminary injunction, should take into account, when they are relevant, (3) the possibility of harm to other interested persons from the grant or denial of the injunction, and (4) the public interest.'" *Reilly v. City of Harrisburg*, 858 F.3d 173, 176 (3d Cir. 2017), *as amended* (June 26, 2017) (quoting *Del. River Port Auth. v. Transamerican Trailer Transport, Inc.*, 501 F.2d 917, 919-20 (3d Cir. 1974)). The Third Circuit employs a "balancing" approach under which a plaintiff "must meet the threshold for the first two 'most critical' factors." *Id.* at 177, 179 (footnotes omitted).

Plaintiff's request to enjoin the FDA from printing or publishing statements regarding its Inspection is fatally flawed for one paramount reason. Simply stated, the FDA does not require judicial approval to carry out the authority delegated to it by Congress as articulated in 21 U.S.C.A. § 375(b). The Court recognizes Plaintiff's argument that the issuance of the Notice or press release is imminent and itself will cause harm; however, the Court declines the invitation to

continue to "press the pause button" without the ability to review the content of any publication and assess whether any irreparable harm will result.

Finally, Plaintiff's First Amendment retaliation claim is wanting of factual development. To this end, Plaintiff concedes, as it must, that to proceed on the First Amendment retaliation claim some discovery is necessary. Absent any evidence that the Notice or press release represent retaliatory conduct, the case for injunctive relief on this issue falls short. For this reason, injunctive relief on this issue is also premature.

V. CONCLUSION

For the reasons set forth above, the Court will lift the temporary restraining order entered on May 6, 2022, and deny any further temporary or preliminary injunctive relief.

Dated: May 19, 2022

s/ Karen M. Williams
KAREN M. WILLIAMS
United States District Judge